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Review

The Obstacles of Valid Informed Consent

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Informed consent refers to the process of giving information, discussing and obtaining permission of patients or participants in terms of medical treatment and human research. Informed consent is the most important right for the patient. However making standardization of valid informed consent is likely to be difficult due to a number of obstacles. On the other hand, courts may require valid informed consent to hold litigation. For this reason, this paper intends to discuss the difficulties in obtaining valid informed consent which is divided into five main elements: disclosure of information, understanding, voluntariness, competence, and consent. This paper will focus on particular situations: emergency cases, critically ill, psychiatric patients, child patients, and human research. This literature review is developed from examining in depth some references such as journal and text book. Chosen references reviewed are study of informed consent particularly in emergency cases, critically ill, psychiatric patients, child patients and human research. The main theory is from Beauchamp, the author of Principle Bioethics. After reviewing this literature it is found that, employing the four aspects of informed consent is likely to be complicated. This may be caused by the condition of patients and participants. People have to deal with some ambiguities of the four aspects of informed consent. There is likely to be conflict between promoting autonomy and the principle of beneficence. Furthermore, the valid informed consent may not be obtained. Therefore, courts have to consider informed consent as a part of legal doctrine for those circumstances. Nonetheless, physicians and researchers have to be aware of the importance of informed consent to grant patients and participants' autonomy and to respect human rights. Informed consent may be seen as part of ethical issues rather than law.

Keyword: Informed, Consent, Valid, Obstacles, Medical, Research, Human rights.

INTRODUCTION

Informed consent refers to the process of giving information, discussing and obtaining permission of patients or participants in terms of medical treatment and human research.

Informed consent have existed in the1940s when human research was conducted in camps concentration by the NAZI. The NAZI medical practitioners did human research without asking consent from the participants. They might assume that they were beneficence for the whole population, because the population would benefit from the result of the research. Therefore they may not require permission (Beauchamp 2003). They may have conformed to consequentialism in that their actions were right, as the consequences were good for whole population. The population may get new drugs to treat certain diseases. Another reason was that the relationship between doctors and patients was such that people allowed the doctors to act on behalf of their patients to achieve better health.

However, other groups held contrary views to the NAZI activities and they found that the doctors did not respect individual's autonomy. Moreover, this group accused the NAZI of intimidating, even exterminating human beings. This group is the Nuremberg medical trial which developed 10 principles of consent, known as the Nuremberg Code (Frewer 2010; Markman and Markman 2007)

Another code which is related to informed consent is the Declaration of Helsinki (1964) which guide physician in human biological research. The Helsinki is based on The Declaration of Geneva of World Medical Association and the International Code of Ethics which are concerned with patients' condition (Helsinki and of Helsinki, 2000).

People tend to refer to these two guidelines because of the complexity of ethical issue in medical treatment

and human research.

In terms of ethical issue, informed consent can be analyzed from two theories: deontological and consequentialist theories. To judge right or wrong actions, deontology concerns duty of the individual, so that from deontology's view, physicians have to inform their action as their duty is to disclose the information of medical processes. Deontology may ignore the consequences of the professional actions. By contrast, the consequentialists tend to focus on the consequences of actions. If a physician does not inform the risks of medical treatment to save patients' life, according to consequentialist, this action may be right. However, Kantz and Capron claim that informed consent may lead to good consequences, such as promoting autonomy patient and protecting human beings and avoiding fraud (Conti et al., 2013; Fields 2008)

Human Rights

Informed consent is related to patients rights in terms of attainment of better health care. From Annas 's point of view (1998), informed consent is the most important right for the patient. Furthermore, in patients' bill of rights, it is stated that patients have rights to get information relating to the medical treatment, to participate in medical treatment, to complain and to appeal. According to Beauchamp and Childress (2009) if someone has the rights, somebody else has the obligation to respect these rights. For example, if freedom is a right, then someone else is obliged to provide freedom, or at least, not to restrict it.

Regarding this idea, doctors have the obligation to provide information and to gain consent from patients before giving medical treatment. A patient could ask a doctor about the side effects of drugs, and also the patient could discuss with the doctor about her/his diseases. Rights and obligations can conflict. Therefore, some rights are likely to become legal rights. Some countries make such an informed consent law (America, Canada, Australia and UK). They make informed consent part of the legal obligation of treatment and research (Maclean 2010a; Satyanarayana Rao 2008).

In addition, making informed consent as part of obligation is likely to promote autonomy of person in terms of medical processes and research (O'Neill 2003; Stoljar 2011). However, this reason is still debatable because informed consent, probably, will not represent the autonomous choices of person due to a number of obstacles, particularly such situations as the following: emergency cases, critically ill, psychiatric patients, child patients, and human research. These obstacles may influence in making standardization of valid informed consent. On the other hand, courts may require valid informed consent to hold litigation (O'Neill 2003). As a consequence, many cases related to negligence or malpractices are unlikely to be held properly by courts. Some people argued that informed consent is not about law, but it is about ethical issue.

For this reason, this paper intends to discuss the difficulties in obtaining valid informed consent which is divided into five main elements: disclosure of information, understanding, voluntariness, competence, and consent. This paper will focus on particular situations: emergency cases, critically ill, psychiatric patients, child patients, and human research

The elements of informed consent

a. Disclosure of Information

To get consent, health professionals and researchers have to disclose information which may cause some confusion or uncertainty because there may be uncertainty about what information should be delivered to the patients and the participants: How much information should be disclosed?

According to The Helsinki Declaration (1964), researchers who work with human beings in their research have to disclose information about benefits, risks and consequences of the research to the participants. Moreover, the Nurumberg Code stated that the participants have to recognize the nature, goal, aim and method of research. Following from the Nurumberg code, O'Neil claimed that the most important aspects which should be explained to patients are the costs and benefits; the researchers do not have to explain the information more detail (cited in Helgesson, 2005)

Benefits, risks and consequences of the research are unlikely to be simple when researchers try to explain to participants. They may deal with some problems in certain circumstances. The first problem is that some researchers may not know the effects of the research. For example, the researchers may not be able to forecast all the side effect of drugs when they do drug trials. The second problem is that some information probably makes participants confused since there are many scientific terms, such as pharmacokinetics of drugs. The third problem is that the amount of information which has been given is unclear (O'Neill, 2003; White and Seery, 2009) for example, testing the effectiveness of drugs. Should researchers or nurses explain the route of drugs when the drugs are administered? Should they explain the nature of drugs which may influence the participants' condition?

In contrast, the simple explanation may not be sufficient for the participants to understand (Fromer, 1981). If the nurses only disclose the benefits and risk of drugs and they do not explain why the drugs cause such side effects or how the drugs work in the body, how will the patients accept the risks, if they do not know the process of drugs metabolism.

Furthermore, delivering information should be considered not only from the materials but also from the

point of view of those who are involved in disclosing the information. In terms of who to involve in disclosing information, there are two standards: professional standards and personal standards. Professional is likely to have standards of which information could be exposed to the patients. However, problems may arise. The physicians tend to disclose information concerning the minor effect of medical treatment to reduce patients' anxiety. In addition, physicians are likely to give information which is medical oriented. On the other hand, patients may need other information which is not medically oriented) (Appelbaum, 2007; Beauchamp and Childress, 2009). For example, when a physician injects drugs into a patient, the physician, probably, will not inform the major risks of the injection because the patient may be scared and s/he may tend to refuse the treatment. The physician tends to conform to the principle of beneficence to promote good and better health conditions (Maclean, 2010b; Paterick et al., 2016)

In terms of personal standard, people have different background and an experience which may influence what they believe is the reasonable standard. People may also need information from physicians to set reasonable standards as they may have difficulties to understand the medical process (Hammami *et al.,* 2014).

b. Understanding

Understanding is very important to get consent from patients. The disclosure of information is unlikely to be useful if the patients and the participants lack understanding(Paterick et al., 2016). The understanding is influenced by many factors, such as knowledge, the level of education, the psychological condition and age. Therefore, patients who are critically ill, in an emergency situation, have a psychosis and or are children may not have a good understanding although they are provided an explanation(Schweickert and Hall, 2005; Van Staden, 2003).

In terms of the psychological condition, some patients are unlikely to understand the information, although nurses or doctors explain with simple language. Not understanding can be caused by having pain, or being unconscious). From normative ethics' perspective, delivering such complex information to these patients may not be appropriate. People may assume that the physician forces information to these patients. According to Maclean, 2010 forcing information may lead to ignore patients' autonomy. Conforming to deontological theories, this action is likely to be wrong. On the other hand, the physicians have duty of disclose information to gain the understanding of patients. The physicians are likely to have a dilemma. They have to do their duty, but, regarding morality, they have to consider patients' condition even though this duty will promote non maleficence to those patients (Beauchamp and Childress, 2009; Beauchamp 2003).

Furthermore, most patients gave their consent because they trusted the doctors. They tend to assume that doctors are virtuous people who have benevolence and compassion. They trusted that doctors were more capable to make decisions because the doctors have good knowledge about diseases and medical process. They would probably put patients on risk (Bernstein, 2005).

c. Competence

Competence refers to the ability of people to do something in terms of psychologically and physically. To give informed consent, people should have competence, which means they have to be in a good condition psychologically and physically because informed consent is related to the understanding of processes, such as medical treatment, human research and surgery. Some reports of human research and surgery stated that the study has followed Helsinki Declaration and all the respondents has provided their informed consent(Isik et al. 2015; Isik et al. 2015).

However, in terms of law 'there is no procedural standard to assess the competence of the patients regarding to the informed consent. This is the main problem, particularly when there is litigation about the medical treatment.

Regarding autonomy, Beauchamp and Childress (2009) said that 'competence is used to refer to a precondition of being able to authorize autonomously*'*. People who act autonomously are competent to give their informed consent. Competence is influenced by knowledge and experiences. For example, medical professionals (doctors and nurses) may give their consent easily when they are the patients and they need some medical treatment. On the other hand they may refuse to get involved in medical trials because they recognize the risks which may exist. By contrast, patients or participants who have little understanding or experience may agree to be involved in the trials or treatment because they think that the doctors will do the best for them. They tend to assume that doctors are virtue. However, medical professionals are human beings who can make mistakes. In addition, the doctors may not be competent to do some treatments. Some general practitioners may take part in an operation even though they are not surgeons.

Some cases involving children and people with schizophrenia have been subject of debate as they related to competence. They may not be competent to give their consent because of cognitive constraints. It is said that psychiatric patients may not have the ability to give informed consent as they have cognitive impairment, so the informed consent may be given by the family. Matza et al. (2006) stated that cognitive impairment tends to influence social behavior, memory and verbal learning; people with schizophrenia, probably cannot analyze and understand procedures. Children, because their brains are still immature, may be under the control of their parents. Therefore, children may not be competent to give consent (Fisher and Oransky, 2008; Helgesson, 2005; Wellesley and Jenkins, 2012). Medical research with a patient in emergency is

questionable as the patients may not be competent because their health condition influences their cognitive ability. They may be unconscious or in great pain.

d. Voluntariness

Voluntariness means people act based on their own mind without force or influence from other circumstances. Voluntariness is the main aspect when people give consent for medical or research purposes. Without voluntariness, informed consent may not be valid.

The person who will give consent should be free from the pressure or influences from other people. They have to make a decision based on their knowledge, information and deceit (Appelbaum *et al*., 2009).

To get knowledge about something, people have to get more information. On the other hand, detailed information about the medical process or research process may cause patients or participants to become confused. Researchers and the medical professional tend to use scientific terms. However, they may find it difficult to use common terms when they explain the process. This causes ambiguity. On the one hand, an adequate understanding about the process encourages voluntariness. On the other hand, giving more detailed information is unlikely to increase the understanding. For this reason, it is difficult to have pure voluntariness for getting consent from the patients.

The ability of people to become volunteers when they make decisions may not be as easy as it is predisposed by many factors. A patient who feels pain, anxiety and worries about their condition may not become a volunteer in research or medical treatment. The agency relationship between doctors and patients may cause the patients to give authority to physicians to do any treatment, because they think doctor is going to do the best for them(Roberts 2002). For example, patients tend to participate in cancer research even though they do not effect of research (Agrawal 2003; Eriksson and Helgesso,n 2005). In spite of beneficence principle, physicians should not coerce patients using their credible position (Beauchamp and Childress, 2009).

Another factor which may interfere is cognitive ability. Child patients and psychiatric patients who become participants in research may not understand about the process, so they have to ask the guardian or parents to represent them to give their consent. It is clear that voluntary in medical process and research is difficult (Roberts 2002).

To get voluntariness from patients, physicians have to avoid coercion, and undue influence. They have to concern the obligation of veracity. It is not voluntariness if the patients make decisions after getting information which only explains about the negative consequences if they do not get the treatment; or, physicians may only recommend one treatment and then, they ask patients to make decision (Beauchamp and Childress, 2009; Fisher, 2013)

e. Consent

Consent refers to action which gives permission for somebody to do something. In terms of human research or medical treatment, consent means patients agree to be involved in such treatment or research processes. The consent can be verbal or in writing. However as a legally document, the consent is in writing and signed by patients, responsible person who will be involved in medical treatment and research. The consent is the end stage of informed consent. Consent after being informed(Maclean 2010b).

DISCUSSION

The valid consent consists of disclosure of information, understanding, competence, and voluntariness. However, some patients or participants do not go through the process before giving their consent (Kerridge *et al*., 2005; Paterick *et al*., 2016). Some of them may not understand processes, some may not have competence and other may give authority to physicians due to paternalistic principle in the medical process.

Obtaining consent is likely to have some difficulties. Asking consent from the parents whose children are critically ill cause the parents to be more stressed. They have to read such procedural treatment which may be difficult to understand (Manning, 2000). Although physicians promote patients' autonomy, the physicians' action may not be beneficence, which oppose to physicians obligation, for the parents.

By contrast, Hayman et al. (2001) found that some parents gave their consent as they were unselfish. They are likely to conform to the principle of beneficence for the population. In addition, they felt that they got advantages because their knowledge about their children is health has been improved. Nevertheless, they were not really voluntary because they had influence from family and friends in terms of decision making.

Although in emergency cases, researchers may be not easily get consent, they should disclose information in brief. Lotjonen (2002) said that participants with emergency condition should be given informed consent briefly about the research, and after the patient achieve good condition, the research will explain the procedure more clearly.

Research on a person without the capacity to consent may be undertaken only if the result of the research has the potential to reduce real and direct benefit to his health (Dommel Jr *et al*., 1997).

CONCLUSION

In conclusion, employing the four aspects of informed consent is likely to be complicated. This may be caused by the condition of patients and participants, such as emergency cases, patient with critical illness, patients with psychosis, and children; as well as the method of informed consent and the people who disclose the

information. People have to deal with some ambiguities of the four aspects of informed consent. There is likely to be conflict between promoting autonomy and the principle of beneficence. Furthermore, the valid informed consent may not be obtained. Therefore, courts have to consider informed consent as a part of legal doctrine for those circumstances. Nonetheless, physicians and researchers have to be aware of the importance of informed consent to grant patients and participants' autonomy and to respect human rights. Informed consent may be seen as part of ethical issues rather than law.

REFFERENCES

Agrawal M (2003). "Voluntariness in Clinical Research at the End of Life." *Journal of Pain and Symptom Management* 25(4): S25–32.

Annas GJ (1998). "A National Bill of Patients' Rights." *The New England journal of medicine* 338(10): 695–99.

Appelbaum PS (2007). "Clinical Practice. Assessment of Patients' Competence to Consent to Treatment." *The New England journal of medicine* 357: 1834–40.

Appelbaum PS, Lidz CW, Klitzman R (2009). "Voluntariness of Consent to Research: A Conceptual Model." *Hastings Center Report* 39(1): 30–39.

Beauchamp TL, Childress JF (2009). "Principles of Medical Ethics." *Oxford University Press*: 459.

Beauchamp TL (2003). "Methods and Principles in Biomedical Ethics." *Journal of Medical Ethics* 29 (5): 269–74.

Bernstein M (2005). "Fully Informed Consent Is Impossible in Surgical Clinical Trials." *Canadian journal of surgery* 48(4): 271.

Conti A, Paola D, Laura L, Corrado P (2013). "Consent in Dentistry: Ethical and Deontological Issues." *Journal of medical ethics* 39(1): 59–61. http://jme.bmj.com/content/39/1/59.abstract.

Dommel Jr FW, Duane A, William Dommel F (1997). "The Convention on Human Rights and Biomedicine of the Council of Europe." *Kennedy Institute of Ethics journal* 7(3): 259–76.

Eriksson S, Helgesson G (2005). "Keep People Informed or Leave Them Alone? A Suggested Tool for Identifying Research Participants Who Rightly Want Only Limited Information." *J Med Ethics* 31(11): 674–78.

Fields K (2008). "Case Two: A Kantian Approach to the Morality of Blood Substitute Clinical Trials without Informed Consent." *Clinical laboratory science : journal of the American Society for Medical Technology* 21(2): 120–21.

Fisher, and Matthew Oransky. 2008. "Informed Consent to Psychotherapy: Protecting the Dignity and Respecting the Autonomy of Patients." *Journal of Clinical Psychology* 64(5): 576–88.

Fisher JA (2013). "Expanding the Frame Of 'voluntariness' in Informed Consent: Structural Coercion and the Power of Social and Economic Context." *Kennedy Institute of Ethics journal* 23(4): 355–79.

Frewer A (2010). "Human Rights from the Nuremberg Doctors Trial to the Geneva Declaration. Persons and Institutions in Medical Ethics and History." *Medicine, Health Care and Philosophy* 13(3): 259–68.

Muhammad H, Al-Jawarneh Y, Al Qadire M (2014). "Information Disclosure in Clinical Informed Consent: 'reasonable' patient's Perception of Norm in High-Context Communication Culture." *BMC Medical Ethics* 15(1): 3. http://www.biomedcentral.com/1472-6939/15/3.

Hayman RM, Taylor BJ, Peart NS, Galland BC, Sayers RM (2001). "Participation in Research: Informed Consent, Motivation and Influence." *Journal of Paediatrics and Child Health* 37(1): 51–54.

Helgesson G (2005). "Children, Longitudinal Studies, and Informed Consent." *Medicine, Health Care and Philosophy* 8(3): 307–13.

Helsinki., The Declaration of, and The Declaration of Helsinki (2000). *World Medical Association.The Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects.*

Isik A, Peker K, Soyturk M, Firat D, Yoruker U, Yilmaz I (2015). "Diagnostic Evaluation and Treatment of Patients with Rectus Abdominis Hematoma." *Cir Esp* 93: 580–88.

Isik A, Peker K, Gursul C, Sayar I, Firat D, Yilmaz I, Demiryilmaz I (2015). "The Effect of Ozone and Naringin on Intestinal Ischemia/reperfusion Injury in an Experimental Model." *International journal of surgery (London, England)* 21: 38–44is.

Kerridge I, Lowe M, McPhee J (2005). *Ethics and Law for the Health Professions*.

Lotjonen S (2002). "Medical Research in Clinical Emergency Settings in Europe." *Journal of Medical Ethics* 28(3): 183–87.

Maclean A (2010a). "Autonomy, Informed Consent and Medical Law: A Relational Challenge." *Medical law review* Winter(18): 111–25.

Maclean A (2010b). "Autonomy, Informed Consent and Medical Law: A Relational Challenge." *Medical law review* Winter(18): 111–25.

Manning DJ (2000). "Presumed Consent in Emergency Neonatal Research." *Journal of medical ethics* 26(4): 249–53.

Markman JR, Markman M (2007). "Running an Ethical Trial 60 Years after the Nuremberg Code." *Lancet Oncology* 8(12): 1139–46.

Matza LS, Buchanan R, Purdon S, Brewster-Jordan J, Zhao Y, Revicki DA (2006). "Measuring Changes in Functional Status among Patients with Schizophrenia: The Link with Cognitive Impairment." *Schizophrenia Bulletin* 32(4): 666–78.

O'Neill O (2003). "Some Limits of Informed Consent." *Journal of Medical Ethics* 29(1): 4–7.

Paterick TJ, Geoff VC, Marjorie CA, Timothy EP (2016). "Medical Informed Consent: General Considerations for Physicians." *Mayo Clinic Proceedings* 83(3): 313–19.

Roberts LW (2002). "Informed Consent and the Capacity for Voluntarism. [Review] [86 Refs]." *American Journal of Psychiatry* 159(May): 705–12.

Satyanarayana Rao KH (2008). "Informed Consent: An Ethical Obligation or Legal Compulsion?" *Journal of cutaneous and aesthetic surgery* 1(1): 33–35.

Schweickert W, Hall J (2005). "Informed Consent in the Intensive Care Unit: Ensuring Understanding in a Complex Environment." *Current opinion in critical care* 11(6): 624–28. 1.

Van Staden CW (2003). "Incapacity to Give Informed Consent Owing to Mental Disorder." *Journal of Medical Ethics* 29(1): 41–43.

Stoljar N (2011). "Informed Consent and Relational Conceptions of Autonomy." *Journal of Medicine and Philosophy* 36(4): 375–84.

Wellesley H, Jenkins IA (2012). "Consent in Children." *Anaesthesia and Intensive Care Medicine* 13(5): 240–42.

White Stuart M, Seery J (2009). "Consent: The Law and Ethical Considerations." *Anaesthesia & Intensive Care Medicine* 10(3): 111–14. http://www.sciencedirect.com/science/article/pii/S1472029909000113 (May 17, 2016).\

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